Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Proposed changes to requirements for listed medicine ingredients: Annual low-negligible risk changes 2026-27

Consultation paper

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Introduction

The Therapeutic Goods (Permissible Ingredients) Determination (the 'Permissible Ingredients Determination') is a legislative instrument under section 26BB of the *Therapeutic Goods Act 1989* (the Act). This instrument specifies all the ingredients that are available for use in listed and assessed listed medicines and their associated requirements. Listed medicines, except for assessed listed medicines, are low-risk products that are not pre-market assessed by the TGA for their quality, safety, and efficacy. To ensure listed medicines can be safely used by consumers, they may only contain pre-approved low-risk ingredients that are specified in the Permissible Ingredients Determination, which have been evaluated for their quality and safety to determine their suitability for use in listed and assessed listed medicines. The Permissible Ingredients Determination is continually reviewed by the TGA to ensure that all ingredients and their requirements are appropriate for use in low-risk medicines.

Purpose

The proposed ingredient changes in this consultation have been reviewed and categorised as being of low-negligible risk. A low-negligible risk change to the Permissible Ingredients Determination is where a delay is unlikely to cause serious or immediate harm. The TGA is seeking the views of relevant stakeholders including consumers, health professionals, industry, and other interested parties on these proposed changes to ensure that all relevant information, evidence and considerations are available to the Delegate of the Minister before they make their decision. Subject to any revisions of the proposals and consideration by the Delegate of the Minister, changes to the Permissible Ingredients Determination are anticipated to commence on 7 June 2027. Sponsors of listed medicines will be provided with a 12-month transition period from the commencement of the Permissible Ingredients Determination to align their products with any changes that changes are made.

Proprietary ingredients

Sponsors and proprietary ingredients (PI) suppliers should consider whether the ingredients covered under the current consultation are included in PIs used in listed medicines.

Sponsors who choose to use PIs in their medicines are responsible for verifying with PI suppliers whether the ingredients within the PIs comply with the current or future listing requirements. Sponsors should have appropriate arrangements with PI suppliers to ensure compliance with all legal obligations.

Transition expectations

Transition periods provide sponsors of existing listed medicines with time to make the necessary arrangements to bring their products into compliance. Sponsors should ensure that no product is **released for supply** after the expiry of the transition period, unless that product (including the details in the Australian Register of Therapeutic Goods [ARTG] listing) is compliant with any new applicable requirements. After the expiry of the transition period, the TGA may select relevant medicines for review to determine whether they comply with the new requirements. Failure to comply by the specified date may result in compliance or enforcement action, consistent with the TGA's regulatory compliance framework.

Proposed changes to requirements for listed medicine ingredients

1. *Myristica fragrans* use during pregnancy and lactation

Background

Myristica fragrans and related ingredients (including nutmeg oil, nutmeg powder, nutmeg dry, mace, and mace oil) are permitted for use in listed medicines. Existing regulatory controls for *Myristica fragrans* and related ingredients under the Permissible Ingredients Determination include mandatory limits on safrole content, container size restrictions, and the use of restricted-flow inserts for high-concentration oils. These measures were established to address acute and general toxicological risks associated with use and accidental ingestion.

Nutmeg and mace have a long history of dietary use; however, several reputable traditional medicine and ethnobotanical sources describe their use as emmenagogues and abortifacients, particularly at high doses. These historical uses, while not reflective of current therapeutic indications, represent a longstanding signal relevant to reproductive safety assessment. Scientific evidence is limited but includes animal data and case reports indicating potential reproductive effects, foetal or neonatal exposure, and biologically plausible mechanisms for reproductive toxicity at medicinal exposures.

Adverse event reporting in Australia and internationally has not identified a clear signal of pregnancy-related harm associated with listed medicines containing *Myristica fragrans* and related ingredients, although under-reporting and limited pregnancy exposure restrict the certainty of these findings. International regulatory frameworks similarly focus on general toxicity or safrole-related risks, with limited explicit consideration of reproductive safety.

No pregnancy or lactation-specific warning statements are currently required for listed medicines containing *Myristica fragrans* or related ingredients under the Permissible Ingredients Determination.

Nutmeg in food is not regulated by the TGA, however the TGA acknowledges the issue discussed in this paper relates to more concentrated constituents of nutmeg and related ingredients than that consumed as part of the average human diet, leading to potential safety concerns.

In this context, the TGA is now consulting on additional risk mitigation measures to adequately protect pregnant and lactating consumers.

Adverse event reports

Australia

As of 1 October 2026, four adverse events have been reported in the TGA Database of Adverse Event Notifications (DAEN) involving products containing *Myristica fragrans*. Two reports related to topical use of nutmeg oil, and two involved solid oral dosage forms containing *Myristica fragrans*. None of the reported events were associated with abortifacient or emmenagogue activity.

International (VigiLyze)

A search of the VigiLyze database (VigiBase[i]) conducted on 1st October 2026 identified 21 international reports of adverse effects in consumers who had used products containing *M. fragrans* as an active ingredient. No reports involved abortifacient or emmenagogue effects.

[i] VigiBase, the WHO global database of reported potential side effects of medicinal products, is developed and maintained by Uppsala Monitoring Centre (UMC).

Health Canada

A search of Health Canada's Canada Vigilance Adverse Reaction Online Database on 1 October 2026 identified three reports associated with products containing *Myristica fragrans*, none of which related to reproductive outcomes.

It is noted that use of complementary medicines may not always be disclosed to pregnancy care providers, reflecting a common perception that such products are inherently safer than conventional medicines. Consequently, spontaneous adverse event reporting systems are subject to under-reporting and lack of exposure data, limiting their ability to reliably detect pregnancy-related risks.

Literature review

Myristica fragrans has long been described in traditional medical systems as an emmenagogue and abortifacient, although this characterisation is based largely on historical accounts rather than controlled human studies. References to the traditional use of *Myristica fragrans* as an abortifacient and/or emmenagogue are reported in traditional medicine and review literature (Asgarpanah & Kazemivash, 2012; Barman et al., 2021; Somani et al., 2008; Al-Rawi et al., 2024). *Myristica fragrans* has also been included in multi-herb preparations used orally in early to mid-pregnancy for the purpose of inducing abortion (Maiti et al., 2011).

Animal studies indicate potential reproductive effects. In female Wistar rats, ethanolic seed extract caused dose-dependent reductions in oestrogen and progesterone without histopathological changes, suggesting endocrine modulation rather than direct foetal toxicity (Uchendu and Ofulue, 2025). In male Wistar rats, 60-day treatment with *Myristica fragrans* oil caused reduced fertility, sperm motility and density, serum testosterone levels, and weights of testes, epididymis, seminal vesicle, ventral prostate and vas deferens; these effects were at least partially reversible as many of these effects improved following 120-day recovery period post-treatment (Agarwal et al. 2009). Toxicology Report 95 from the United States National Toxicology Program (NTP) found reduced epididymal weight and sperm counts in rats exposed to myristicin, indicating impaired sperm maturation (NTP, 2019).

Overall, scientific evidence remains limited, with few well-designed reproductive toxicity studies and no robust human clinical data. Traditional abortifacient use is therefore best considered a signal of potential risk than confirmed pharmacological activity.

Certain constituents derived from *Myristica fragrans* (myristicin, and acetone extracts of mace and nutmeg) have been reported to cause DNA adducts when administered to mice, and myristicin has been demonstrated to cause DNA adducts in developing foetuses when administered to pregnant mice (Randerath et al., 1993). The potential for developmental toxicity has been demonstrated in a zebrafish model, in which direct exposure to *Myristica fragrans* essential oil reduced embryo survival in a dose-dependent manner (Sun et al., 2023). A study performed in mice demonstrates the potential for transmammary transfer of *Myristica fragrans*, with altered liver enzyme activity in offspring following maternal exposure (Chhabra & Rao, 1994).

The Select Committee on GRAS Substances (SCOGS) also noted that large doses of nutmeg (≥10 g) have historically been associated with toxicity and abortifacient use (SCOGS Report No. 18. U.S. Food and Drug Administration, 1973). By contrast, a Flavor and Extract Manufacturers Association (FEMA) GRAS assessment (Davidsen et al., 2023) reported on a study documenting three separate oral toxicity studies in female Wistar rats, CD-1 mice and golden hamsters (Morgareidge, 1973). The studies showed that administration of nutmeg oil in Wistar rats at up to 260 mg/kg bw /day did not result in any effects on maternal or foetal survival or the development of the foetuses. Administration of nutmeg oil in CD-1 mice and hamsters of 560 mg/kg bw/day was shown to have no effects on maternal or foetal development. Administration of nutmeg oil in golden hamsters of 600mg/kg bw/day

did not result in any adverse effect to dams or foetuses of treated groups (Davidsen et al., 2023; Morgareidge, 1973).

Taken together, available evidence from scientific literature suggests *Myristica fragrans* may affect reproductive processes, with uncertainties regarding safety at medicinal doses in pregnancy and lactation. In the absence of adequate human data, the TGA is proposing a precautionary approach, noting abortifacient signals in traditional literature, and scientific evidence of endocrine effects, and placental and lactational transfer.

The Natural Medicines Database (NatMed Pro; McGuffin et al., 1997) classifies nutmeg and mace as "possibly unsafe" when used orally in medicinal amounts during pregnancy, citing historical use and toxicological concerns including safrole-associated genotoxicity. It advises avoiding medicinal doses during pregnancy and breastfeeding due to insufficient safety data.

Ethnobotanical records, including Maiti et al., 2013 and Dr. Duke's Phytochemical and Ethnobotanical Databases, similarly document traditional abortifacient use across regions. The German Commission-e-monograph acknowledges such effects at high, non-dietary doses linked to general toxicity and concludes therapeutic use is not justified due to limited efficacy and safety concerns. However, it distinguishes this from safe use as a flavouring within normal dietary intake.

Overall, these data and regulatory evaluations support a precautionary approach to medicinal-dose use of *Myristica fragrans* during pregnancy and lactation, particularly in the absence of robust human safety data.

International regulation

Australian Industrial Chemicals Introduction Scheme (AICIS)

Myristica fragrans extract and its derivatives (e.g. essential oils, oleoresins, distillates) under CAS 84082-68-8 are listed on the Industrial Chemicals Inventory with no restrictions on import or manufacture.

Health Canada

Health Canada limits oral use of nutmeg (seed powder or extract) to 33.6 mg/day, allows kernel oil up to 0.8% topically, and requires minimum homeopathic potencies (generally ≥1X). The Natural Health Product Ingredient Database (NHPID) permits *Myristica fragrans* and related substances as medicinal ingredients for oral and topical use without restrictions. As non-medicinal ingredients, nutmeg is limited to flavouring (oral, ≤33.6 mg/day), while extracts and kernel oil are restricted to topical use (kernel oil ≤0.8%). Homeopathic entries are permitted with specified preparation methods and minimum potencies.

Food and Drug Administration (FDA)

Nutmeg, mace and their essential oils, oleoresins and natural extractives are listed as Generally Recognized as Safe (GRAS) for their intended use as food flavourings/seasonings under US FDA regulations, including 21 CFR 182.10 and 182.20. Nutmeg and mace were reviewed by SCOGS (SCOGS Report No. 18. U.S. Food and Drug Administration, 1973) and assigned a Type 3 conclusion, indicating that no hazard was demonstrated at then-current levels and conditions of use, but that uncertainties remained requiring additional studies. In 2023 they were evaluated by FEMA (Davidsen et al., 2023) for flavour use only (excluding dietary supplements). Available data, including teratology studies, did not show adverse developmental effects at tested levels.

European Chemicals Agency (ECHA)

Extracts of Myristica fragrans (Myristica fragrans, ext.) is pre-registered under Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) with multiple active registrations for the purpose of import and manufacture of products. Industry-supplied hazard classifications include potential for aspiration toxicity, skin allergic reactions, carcinogenicity, genotoxicity, flammability, and aquatic toxicity.

European Food Safety Authority (EFSA)

EFSA assessed nutmeg oil as an animal feed additive and found low concern for long-living and reproductive animals at 0.2–2.5 mg/kg feed (EFSA Panel on Additives and Products or Substances used in Animal Feed, et al. 2023). The TGA notes that this assessment is specific to animal use and may not be directly applicable to humans.

Advisory Committee on Complementary Medicines

At its 34th meeting, advice was sought on whether ACCM considered the evidence presented in the safety review for *Petroselinum crispum* (parsley) sufficient for products containing parsley to be contraindicated for use in pregnancy (due to the presence of apiol and myristicin). ACCM agreed evidence was sufficient and provided the following advice regarding an appropriate approach to safety assessment for other herbs containing apiol and/or myristicin:

- Safety assessment should be based on whole-herb risk, not individual constituents.
- Among herbs containing similar compounds, nutmeg posed the highest priority due to its relatively higher myristicin content.

At its 36th meeting, advice was sought on whether ACCM considered the available evidence presented in the safety review for *Myristica fragrans* sufficient for products containing *Myristica fragrans* to be contradicted for use in pregnancy. ACCM advised, given the lack of scientific evidence, that more information on traditional approaches to use and information on dosage of products in market was required.

Additional information, including expert advice from practitioners in Ayurvedic, Traditional Chinese, South American and Western herbal medicine, a review of ARTG-listed products containing *Myristica fragrans* and an evaluation of traditional literature and toxicological case reports were considered at ACCM's 38th meeting. Traditional medicine experts advised that *Myristica fragrans* is not traditionally recognised as an abortifacient or emmenagogue within codified Ayurvedic or Traditional Chinese Medicine sources, although historical references to such uses have been described in some ethnomedical and non-codified traditional medicine literature. Advice from Western herbal medicine experts indicated that historical references to abortifacient and emmenagogue use exist but are not reflected in contemporary Western herbal medicine sources. Experts also emphasised caution regarding high-dose use during pregnancy and lactation, with some considering medicinal doses of nutmeg and its extracts to be contraindicated during these periods. ACCM were asked to advise on the benefit–risk balance of *Myristica fragrans'* use by pregnant and lactating women and appropriate risk mitigation measures. The Committee supported implementing a cautionary label warning to not use if pregnant or likely to become pregnant, or during lactation.

The Committee agreed that cut-off limits should be established to exempt low-dose products from the warning and supported exemption of the warning for low-dose preparations such as homeopathic products and proprietary flavour/ fragrance formulations, considering the miniscule amounts in such preparations.

Consultation

In line with the recommendation from the 38th meeting of ACCM and, additionally, noting evidence of lactational transfer in combination with uncertainties regarding safety at medicinal doses in pregnancy and lactation, the TGA is proposing to introduce the requirement for the following warning statement to be included on the labels of product that contain *Myristica fragrans* or its related ingredients:

'If you are lactating, pregnant, or considering becoming pregnant, do not take without consulting a health professional.' (or words to that effect).

The proposed warning would apply to medicines containing the relevant ingredient regardless of route of administration but would not apply in cases where the relevant ingredient is used as part of a proprietary ingredient (PI) formulation for flavouring or fragrance or where the ingredient is used as part of a homoeopathic preparation prepared to a potency of more than 12X.

The basis for the warning not being required in cases where the ingredient is being combined with other permissible ingredients as a fragrance or flavour proprietary excipient formulation, is that as the proprietary excipient formulations are limited to a maximum of 5% of the medicine formulation (for flavours) and 1% of the medicine formulation (for fragrances). Given that risks of use are associated with large doses of the ingredient (noting that large doses can be considered to be doses ≥10 grams (SCOGS-Report Number 18, U.S. Food and Drug Administration; 1973.), the restrictions inherent in using the ingredient as an FFPI are sufficient to mitigate the risk associated with use of the ingredient.

The proposed cut-off limit for application of the label warning to homoeopathic preparations is based on the principle that highly diluted homoeopathic products for oral use and topical for dermal use would be unlikely to pose a risk to consumers. Therefore, a warning statement will not be necessary for preparations containing homoeopathic potencies more dilute than 12X.

As part of this consultation, the TGA is seeking feedback on:

a) the suitability of the wording of the proposed warning statement,
b) whether the proposed risk mitigation is appropriate and proportionate to the identified risk, and
c) whether low risk uses (in flavour and fragrance proprietary ingredients used at concentrations of up to 5% for flavours and up to 1% for fragrances, and homoeopathic preparations prepared to a potency of more than 12X) should be exempt from the requirement to include the warning statement on product labels of listed medicines.

In addition, the TGA welcomes feedback on the potential impact of the proposed warning on medicine sponsors, consumers and regulatory compliance activities, as well as any additional data, evidence or information sources that should be considered in evaluating this proposal.

Affected ingredients

- MYRISTICA FRAGRANS
- MACE OIL
- MACE
- NUTMEG DRY
- NUTMEG OIL
- NUTMEG POWDER

As of 12 October 2026, the ARTG includes the following entries related to Myristica fragrans:

- 4 medicines containing Myristica fragrans as an active ingredient.
- 2 medicines containing Nutmeg oil as an active ingredient.
- 4 medicines containing Nutmeg oil as an excipient.
- 42 medicines containing Nutmeg oil as part of a flavour or fragrance proprietary ingredient.
- No medicines containing Mace, Mace oil, Nutmeg Dry, or Nutmeg Powder.

Proposed specific requirements

Ingredient	Purpose	Proposed requirements[ii]
MYRISTICA FRAGRANS	A, E, H	Safrole is a mandatory component of Myristica fragrans. ~~When for internal use then~~Where used internally, the concentration of safrole in ~~the~~a medicine must ~~be no more than~~not exceed 0.1%. ~~When for topical use then~~Where used topically, the concentration of safrole in ~~the~~a medicine must ~~be no more than~~not exceed 1%. ~~When~~Where the plant preparation is oil or distillate and the concentration of Myristica fragrans in ~~the~~ a medicine ~~is more than~~exceeds 50%, the nominal capacity of the container must ~~be no more than~~ not exceed 25 millilitres, the medicine must have a restricted flow insert fitted on the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or word to that effect). The total concentration of flavour proprietary excipient formulations must not exceed 5% of the medicine. The total concentration of fragrance proprietary excipient formulations must not exceed 1% of the medicine. The following warning statement must be included on the medicine label: - 'If you are lactating, pregnant, or considering becoming pregnant, do not take without consulting a health professional.' (or words to that effect) unless where Myristica fragrans is used as: (a) an active homoeopathic ingredient at a homoeopathic potency of more than 12X; or (b) an excipient in a flavour; or (c) an excipient in a fragrance.
MACE OIL	A, H	Safrole is a mandatory component of Mace oil. Where~~n~~ used internally, the concentration of safrole in ~~the~~a medicine must ~~be no more than~~ not exceed 0.1%. Where~~n~~ used topically, the concentration of safrole in ~~the~~a medicine must ~~be no more than~~ not exceed 1.0%. Where~~n~~ the concentration of ~~m~~Mace oil in ~~the preparation~~a medicine ~~is more than~~exceeds 50% and the nominal capacity of the container ~~is~~does not exceed 25 millilitres~~mL or less~~, the medicine must have a restricted flow insert ~~must be~~ fitted on the container. The following warning statement must be included on the medicine label: - 'If you are lactating, pregnant, or considering becoming pregnant, do not take without consulting a health professional.' (or words to that effect) unless where mace oil is used as an active homoeopathic ingredient at a homoeopathic potency of more than 12X.

[ii] Current specific requirements are in black font, addition in green font and deletion strikethrough in red font.

Ingredient	Purpose	Proposed requirements[ii]
MACE	E	Safrole is a mandatory component of Mace. Where~~n~~ used internally, the concentration of safrole in ~~the~~a medicine must ~~be no more than~~ not exceed 0.1%. Where~~n~~ used topically, the concentration of safrole in ~~the~~a medicine must ~~be no more than~~ not exceed 1.0%. The total concentration of flavour proprietary excipient formulations must not exceed 5% of the medicine. The total concentration of fragrance proprietary excipient formulations must not exceed 1% of the medicine. The following warning statement must be included on the medicine label: - 'If you are lactating, pregnant, or considering becoming pregnant, do not take without consulting a health professional.' (or words to that effect) unless where mace is used as: (a) an excipient in a flavour; or (b) an excipient in a fragrance.
NUTMEG DRY	A, E, H	Safrole is a mandatory component of Nutmeg Dry. ~~When for internal use then~~Where used internally, the concentration of safrole in ~~the~~a medicine must ~~be no more than~~not exceed 0.1% ~~When for topical use then~~Where used topically, the concentration of safrole from all ingredients in ~~the~~a medicine must ~~be no more than~~not exceed 1%. The total concentration of flavour proprietary excipient formulations must not exceed 5% of the medicine. The total concentration of fragrance proprietary excipient formulations must not exceed 1% of the medicine. The following warning statement must be included on the medicine label: - 'If you are lactating, pregnant, or considering becoming pregnant, do not take without consulting a health professional.' (or words to that effect) unless where nutmeg dry is used as: (a) an active homoeopathic ingredient at a homoeopathic potency of more than 12X; or (b) an excipient in a flavour; or (c) an excipient in a fragrance.

Ingredient	Purpose	Proposed requirements[ii]
NUTMEG OIL	A, E, H	Safrole is a mandatory component of Nutmeg oil. ~~When for internal use then~~Where used internally, the concentration of safrole in ~~the~~a medicine must ~~be no more than~~not exceed 0.1%. ~~When for topical use then~~Where used topically, the concentration of safrole in ~~the~~a medicine must ~~be no more than~~not exceed 1%. ~~When~~Where the concentration of Nutmeg oil in ~~the~~a medicine ~~is more than~~exceeds 50%, the nominal capacity of the container must ~~be no more than~~not exceed 25 millilitres~~mL~~, the medicine must have a restricted flow insert fitted on the container and requires the following warning statement on the medicine label: - (CHILD) 'Keep out of reach of children' (or words to that effect). The total concentration of flavour proprietary excipient formulations must not exceed 5% of the medicine. The total concentration of fragrance proprietary excipient formulations must not exceed 1% of the medicine. The following warning statement must be included on the medicine label: - 'If you are lactating, pregnant, or considering becoming pregnant, do not take without consulting a health professional.' (or words to that effect) unless where nutmeg oil is used as: (a) an active homoeopathic ingredient at a homoeopathic potency of more than 12X; or (b) an excipient in a flavour; or (c) an excipient in a fragrance.
NUTMEG POWDER	A, E, H	Safrole is a mandatory component of Nutmeg powder. ~~When for internal use then~~Where used internally, the concentration of safrole in ~~the~~a medicine must ~~be no more than~~not exceed 0.1%. ~~When for topical use then~~Where used topically, the concentration of safrole in ~~the~~a medicine must ~~be no more than~~not exceed 1%. The total concentration of flavour proprietary excipient formulations must not exceed 5% of the medicine. The total concentration of fragrance proprietary excipient formulations must not exceed 1% of the medicine. The following warning statement must be included on the medicine label: - 'If you are lactating, pregnant, or considering becoming pregnant, do not take without consulting a health professional.' (or words to that effect) unless where nutmeg powder is used as: (a) an active homoeopathic ingredient at a homoeopathic potency of more than 12X; or (b) an excipient in a flavour; or (c) an excipient in a fragrance.

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2. Requirements relating to amygdalin and hydrocyanic acid

Background

In keeping with their role as low-risk medicines, listed medicines must not contain a substance included in a Schedule to the Poisons Standard (Schedule 4, Item 3(ca) of the Therapeutic Goods Regulations 1990), and must be certified to contain only ingredients specified in the Permissible Ingredients Determination (paragraphs 2(ca) and 2(cb); section 26A of the Act). Some substances included in the Poisons Standard (also known as the *Standard for the Uniform Scheduling of Medicines and Poisons* [SUSMP]) are subject to scheduling thresholds below which they are not scheduled. Substances that are not included in a Schedule to the Poisons Standard are therefore not prohibited for use in listed medicines.

Some specific requirements for ingredients in the Permissible Ingredients Determination include quantity restrictions on components within ingredients. These 'mandatory components' help support compliance with thresholds for inclusion in a Schedule to the Poisons Standard and provide greater oversight of these components within finished listed medicine products. Specific requirements that include mandatory components require medicine sponsors to quantify the component and declare the content during the listing process in the Electronic Listing Facility (ELF).

Recent changes to the Poisons Standard have increased the limit below which amygdalin and hydrocyanic acid are not scheduled, and hence the requirements within the Permissible Ingredients Determination relating to these substances as components within ingredients should be aligned to ensure consistency across legislative instruments. Some ingredient requirements have already been updated to align with the revised Poisons Standard thresholds as the changes were more permissive and did not result in regulatory impact to any existing medicine. This consultation seeks input on new restrictions to other ingredients that have been identified as containing amygdalin and hydrocyanic acid as components. These new requirements are intended to align with existing requirements in the Permissible Ingredients Determination for other ingredients containing these components.

Poisons Standard entries for amygdalin and hydrocyanic acid

In the June 2025 update to the Poisons Standard (Therapeutic Goods (Poisons Standard—June 2025) Instrument 2025), the entries for amygdalin and hydrocyanic acid were amended. These changes were detailed in the Notice of final decision to amend (or not amend) the current Poisons Standard – amygdalin, hydrocyanic acid and Wild Cherry Bark, Joint ACMS ACCS #34 and implemented 1 June 2025.

As at time of this consultation, the relevant schedules in the Therapeutic Goods (Poisons Standard—June 2026) Instrument 2026 are as follows:

Amygdalin

Schedule 10

AMYGDALIN for therapeutic use **except** in preparations containing 10 mg/kg or less of amygdalin.

Hydrocyanic acid

Schedule 7 HYDROCYANIC ACID **except**:

(a) when included in Schedule 4; or

(b) its salts and derivatives other than cyanides separately specified in this Schedule; or

(c) in preparations containing 10 mg/kg or less of hydrocyanic acid.

Schedule 4

HYDROCYANIC ACID for therapeutic use **except** in preparations containing 10 mg/kg or less of hydrocyanic acid.

The amendments result in amygdalin and hydrocyanic acid being unscheduled when for therapeutic use in preparations containing 10 mg/kg or less of these substances. Prior to this, amygdalin was included in Schedule 10 (prohibited from sale, supply and use) and was not included in Appendix G (Dilute Preparations). Consequently, there was no concentration below which scheduling did not apply, and amygdalin was therefore not permitted in listed medicines at any concentration.

Hydrocyanic acid was included in Schedules 4 and 7, and in Appendices F, G and J. The Appendix G entry provided an exemption from scheduling only where the concentration did not exceed 1 microgram per litre or kilogram. Consequently, hydrocyanic acid could only be present in listed medicines at concentrations below this level.

Restrictions in the Permissible Ingredients Determination relating to amygdalin and hydrocyanic acid

Amygdalin is a cyanogenic glycoside, a category of compounds that are naturally occurring sugars produced by many plants, and which contain cyanide within their chemical structure (Food Standards Australia New Zealand 2014). Cyanogenic glycosides, including amygdalin, exhibit considerable toxicity due the production of hydrocyanic acid (HCN, also known as hydrocyanic acid) following hydrolysis, which may occur in medicines due to manufacturing processes or ingestion (Joint FAO/WHO Expert Committee on Food Additives 2012, Food Standards Australia New Zealand 2014). While toxicity is dose related, there is also significant inter-individual variability. These were the bases of the current scheduling entries for amygdalin and hydrocyanic acid in the Poisons Standard[iii,iv]. The TGA proposes that specific requirements should be implemented for both components concurrently as amygdalin acts as a precursor to hydrocyanic acid, which is the substance of primary toxicological concern (Bolarinwa et al. 2016, EFSA Panel on Contaminants in the Food Chain et al. 2019).

Currently, twenty-two ingredients in the Permissible Ingredients Determination have specific requirements relating to hydrocyanic acid and/or amygdalin (**Appendix A – Ingredients in Permissible Ingredients Determination No. 2 of 2026 with requirements relating to hydrocyanic acid and/or amygdalin**). In the second update to the Permissible Ingredients Determination of 2025 the specific requirements for 20 of these ingredients were modified to align with the Poisons Standard changes relating to amygdalin and hydrocyanic acid. The updated requirements allowed higher quantities of these two components; i.e. where amygdalin was limited to a concentration of 0%, this was amended to allow not more than 10 mg/kg, and where hydrocyanic acid was limited to 1 microgram per kilogram or litre, this was amended to the new limit of not more than 10 mg/kg.

Two ingredients (**Malus domestica**, ingredient ID 108206, and **bitter almond oil**, ingredient ID 102790) were not modified to align with the revised Poisons Standard as part of the second update to the Permissible Ingredients Determination of 2025 because such an alignment would have introduced more stringent requirements for these ingredients. Although the same controls already apply through the operation of the Poisons Standard, public consultation is required before those requirements can be expressly included in the Permissible Ingredients Determination.

Internal review by the TGA indicates that the specific requirements applying to **Malus domestica** and **bitter almond oil** have been inconsistent with those applying to other ingredients that may contain amygdalin or hydrocyanic acid since development of the inaugural Permissible Ingredients Determination (No. 1 of 2015). Although the requirements differed in wording, they were functionally equivalent at the time because they effectively restricted amygdalin content to 0%. As a result, the inconsistency did not lead to materially different regulatory outcomes. Following the recent

[iii] Notice of interim decisions to amend (or not amend) the current Poisons Standard
[iv] Notice of interim decisions to amend (or not amend) the current Poisons Standard, ACMS #34

amendment of the Poisons Standard threshold for amygdalin and hydrocyanic acid, however, the differing requirements now result in different regulatory outcomes for otherwise comparable ingredients. The TGA therefore proposes to amend the specific requirements for these two ingredients to permit amygdalin and hydrocyanic acid at concentrations of not more than 10 mg/kg and to include amygdalin and hydrocyanic acid as mandatory components, consistent with the approach adopted for comparable ingredients.

For **Malus domestica** and **bitter almond oil**, addition of amygdalin as a mandatory component is now necessary to enable Electronic Listing Facility (ELF) validations on total amygdalin content in final preparations. The ELF validations will ensure amygdalin content remains below Poisons Standard limits and prevent non-listable products (i.e. those with total amygdalin content greater than 10 mg/kg) from becoming listed on the ARTG.

Similarly, due to the potential for amygdalin to be converted to hydrocyanic acid under certain processing conditions (Food Standards Australia New Zealand 2014), TGA is proposing to add hydrocyanic acid as a mandatory component to **Malus domestica** and **bitter almond oil,** and to restrict the quantity below 10 mg/kg. Adding hydrocyanic acid as a mandatory component with a 10mg/kg quantity restriction to **Malus domestica** and **bitter almond oil** would support compliance with the relevant Poisons Standard threshold and promote consistency with other ingredients in the Determination.

Consistency across related ingredients

To ensure all ingredients which may contain amygdalin and/or hydrocyanic acid have consistent requirements, a search of the Permissible Ingredients Determination was undertaken to identify ingredients that are highly similar to or overlap in definition with those which have already been identified to contain amygdalin and/or hydrocyanic acid. Alignment of requirements for these highly related ingredients ensures that a substance which may be identified under multiple ingredient names is regulated consistently. For the 15 ingredients identified, the requirements are now proposed to be aligned, incorporating mandatory components and limits as follows:

> Amygdalin and hydrocyanic acid are mandatory components of [ingredient name].
>
> The concentration of amygdalin in the medicine must not be more than 10 mg/kg.
>
> The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.

As outlined in TGA approved terminology for therapeutic goods, the identities of all Australian Approved Name ingredients are defined by their naming references, which are displayed on Ingredient Summary documents. The identities of these ingredients were confirmed using their naming references to be of the same or highly related species, or as precursors or derivatives, to ingredients which are already subject to requirements relating to amygdalin and hydrocyanic acid (see Table 1). In some cases, the identified ingredients are named with common terms as Approved Foods Names (AFNs), which identify the same substances as equivalent binomial named Approved Herbal Names (AHNs). For example, the common name ‘apricot’ (AFN; ingredient ID 86934) is considered to identify fruit from the plant ‘Prunus armeniaca’ (AHN; ingredient ID 68555). In the interest of internal consistency of the Determination and consistency of regulation across different ingredient categories, the AFN ingredient requirements should align with the AHN equivalent ingredient requirements.

Table 1 – Ingredients identified as being related to ingredients with specific requirements on amygdalin and/or HCN concentration limits

Identified ingredient (Ingredient ID)	**Rationale**
Malus sylvestris (ID 96553)	Malus sylvestris is related to Malus domestica (ID 108206), both being in the same genus (*Malus*) which is known to produce amygdalin (Haque and Bradbury 2002, Joint FAO/WHO Expert Committee on Food Additives 2012, Bolarinwa et al. 2015).
Apple (ID 86930)	This ingredient is related to Malus domestica (ID 108206) and Malus sylvestris (ID 96553), which have/proposed to have amygdalin and HCN requirements. The definition for the ingredient ‘apple’

	encompasses the fruit from the species Malus domestica (Haque and Bradbury 2002, Joint FAO/WHO Expert Committee on Food Additives 2012, Bolarinwa et al. 2015).
Apple fibre (ID 86179)	This ingredient is related to Malus domestica (ID 108206), which is proposed to have amygdalin and HCN requirements. The definition for the ingredient 'apple fibre' encompasses the fruit from the species Malus domestica.
Apple extract (ID 104677)	AIN related to Malus domestica (ID 108206), which is proposed to have amygdalin and HCN requirements.
Apple essence natural (ID 99502)	This ingredient is related to Apple (ID 86930) and Malus domestica (ID 108206), which have/proposed to have amygdalin and HCN requirements.
Almond (ID 86928)	Related to Prunus dulcis (ID 83438) and Almond oil (ID 52033), both of which have existing amygdalin and HCN requirements.
Plum (ID 86929)	Related to Prunus cerasifera (ID 85462), Prunus domestica (ID 60091), Prunus salicina (ID 91526), Prunus spinosa (ID 83445); all of which have existing amygdalin and HCN requirements
Loquat (ID 96195)	Related to Eriobotrya japonica (ID 75003) which has existing amygdalin and HCN requirements.
Peach (ID 63963)	Related to Prunus persica (ID 68718) which has existing amygdalin and HCN requirements
Cherry (ID 92627)	Related to Prunus avium (ID 91524) and Prunus cerasus (ID 64276), which have existing amygdalin and HCN requirements.
Cherry distillate (ID 91173)	Related to Cherry (ID 92627), Prunus avium (ID 91524) and Prunus cerasus (ID 64276), which have/proposed to have amygdalin and HCN requirements.
Apricot (ID 86934)	Related to Prunus armeniaca (ID 68555) which has existing amygdalin and HCN requirements.
Apricot kernel oil PEG-6 esters (ID 90093)	Related to Prunus armeniaca (ID 68555) and Persic oil (ID 55174), which have existing amygdalin and HCN requirements. The definition of these ingredients overlap with the precursors for precursors for apricot kernel oil PEG-6 esters.

Consultation

Considering the available information, the TGA is proposing to add amygdalin and hydrocyanic acid as mandatory components to the Permissible Ingredient Determination entries of the ingredients listed in Table 1, alongside requirements that restrict the concentration of these components in the final medicine. This would support compliance with the relevant Poisons Standard threshold and promote consistency with other ingredients in the Permissible Ingredients Determination.

The TGA is inviting interested stakeholders to comment on the TGA proposal and submit additional information to support or refute any suggested changes to the proposed requirements.

Following consideration of comments received for this consultation, and subject to any revisions of the proposals and consideration by the Delegate of the Minister, sponsors of existing listed and assessed listed medicines containing the affected ingredients will have until the end of the transition period to amend their products in line with any new requirements.

Affected Ingredients

Ingredients found based on amygdalin in requirements, or are analogous to another ingredient which has amygdalin in requirements

- Malus domestica (ID 108206)
- Bitter almond oil (ID 102790)
- Malus sylvestris (ID 96553)
- Apple (ID 86930)
- Apple fibre (ID 86179)

- Apple extract (ID 104677)
- Apple essence natural (ID 99502)
- Almond (ID 86928)
- Plum (ID 86929)
- Loquat (ID 96195)
- Peach (ID 63963)
- Cherry (ID 92627)
- Cherry distillate (ID 91173)
- Apricot (ID 86934)
- Apricot kernel oil PEG-6 esters (ID 90093)

As of 12 October 2026, there are 118 products listed on the ARTG containing the affected ingredients listed above. These ingredients are used as active and excipient. Of the listed medicines using these ingredients, 112 are for oral route of administration and 3 are for topical administration.

Proposed specific requirements

Ingredient name	Proposed specific requirements[v]
Malus domestica	Amygdalin and hydrocyanic acid are mandatory components of Malus domestica. The concentration of amygdalin in a medicine must ~~be no more than 0%~~not exceed 10 mg/kg. The concentration of hydrocyanic acid in a medicine must not exceed 10 mg/kg.
bitter almond oil	Amygdalin and hydrocyanic acid are mandatory components of bitter almond oil. The concentration of amygdalin in a medicine must ~~be no more than 0%~~not exceed 10 mg/kg. The concentration of hydrocyanic acid in a medicine must not exceed 10 mg/kg. Bitter almond oil must only be included in medicines when ~~in~~ combin~~ation~~ed with other permi~~tted~~ssible ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations ~~containing bitter almond oil~~ must not ~~be more than~~exceed 5% of the medicine.
Malus sylvestris	Amygdalin and hydrocyanic acid are mandatory components of Malus sylvestris. The concentration of amygdalin in a medicine must not exceed 10 mg/kg. The concentration of hydrocyanic acid in a medicine must not exceed 10 mg/kg.
Apple	Amygdalin and hydrocyanic acid are mandatory components of Apple. The concentration of amygdalin in a medicine must not exceed 10 mg/kg. The concentration of hydrocyanic acid in a medicine must not exceed 10 mg/kg.
Apple fibre	Amygdalin and hydrocyanic acid are mandatory components of Apple fibre. The concentration of amygdalin in a medicine must not exceed 10 mg/kg. The concentration of hydrocyanic acid in a medicine must not exceed 10 mg/kg.
Apple extract	Apple extract must ~~Permitted for use~~ only be included in medicines when ~~in~~ combin~~ation~~ed with other permi~~tted~~ssible ingredients as a flavour proprietary excipient formulation. ~~If used in a~~The total concentration of flavour ~~the total flavour concentration~~proprietary excipient formulations~~in a medicine~~ must not~~be no more than~~ exceed 5% of the medicine. Amygdalin and hydrocyanic acid are mandatory components of Apple extract. The concentration of amygdalin in a medicine must not exceed 10 mg/kg. The concentration of hydrocyanic acid in a medicine must not exceed 10 mg/kg.

[v] Current specific requirements are in black font, addition in green font and deletion strikethrough in red font.

Ingredient name	Proposed specific requirements[v]
Apple essence natural	Apple essence natural must ~~Permitted for use~~ only be included in medicines when ~~in~~ combin~~ation~~ed with other permi~~tted~~ssible ingredients as a flavour proprietary excipient formulation. ~~If used in a~~The total concentration of flavour ~~the total flavour concentration~~proprietary excipient formulations~~in a medicine~~ must not~~be no more than~~ exceed 5% of the medicine. Amygdalin and hydrocyanic acid are mandatory components of Apple essence natural. The concentration of amygdalin in a medicine must not exceed 10 mg/kg. The concentration of hydrocyanic acid in a medicine must not exceed 10 mg/kg.
Almond	Amygdalin and hydrocyanic acid are mandatory components of Almond. The concentration of amygdalin in a medicine must not exceed 10 mg/kg. The concentration of hydrocyanic acid in a medicine must not exceed 10 mg/kg.
Plum	Amygdalin and hydrocyanic acid are mandatory components of Plum. The concentration of amygdalin in a medicine must not exceed 10 mg/kg. The concentration of hydrocyanic acid in a medicine must not exceed 10 mg/kg.
Loquat	Amygdalin and hydrocyanic acid are mandatory components of Loquat. The concentration of amygdalin in a medicine must not exceed 10 mg/kg. The concentration of hydrocyanic acid in a medicine must not exceed 10 mg/kg.
Peach	Amygdalin and hydrocyanic acid are mandatory components of Peach. The concentration of amygdalin in a medicine must not exceed 10 mg/kg. The concentration of hydrocyanic acid in a medicine must not exceed 10 mg/kg.
Cherry	Amygdalin and hydrocyanic acid are mandatory components of Cherry. The concentration of amygdalin in a medicine must not exceed 10 mg/kg. The concentration of hydrocyanic acid in a medicine must not exceed 10 mg/kg.
Cherry distillate	Cherry distillate must ~~Permitted for use~~ only be included in medicines when ~~in~~ combin~~ation~~ed with other permi~~tted~~ssible ingredients as a flavour proprietary excipient formulation. ~~If used in a~~The total concentration of flavour ~~the total flavour concentration~~proprietary excipient formulations~~in a medicine~~ must not~~be no more than~~ exceed 5% of the medicine. Amygdalin and hydrocyanic acid are mandatory components of Cherry distillate. The concentration of amygdalin in a medicine must not exceed 10 mg/kg. The concentration of hydrocyanic acid in a medicine must not exceed 10 mg/kg.
Apricot	Amygdalin and hydrocyanic acid are mandatory components of Apricot. The concentration of amygdalin in a medicine must not exceed 10 mg/kg. The concentration of hydrocyanic acid in a medicine must not exceed 10 mg/kg.
Apricot kernel oil PEG-6 esters	Apricot kernel oil PEG-6 esters must ~~O~~only ~~for~~ be used ~~as an excipient~~ in topical medicines for dermal application. (a) Amygdalin and hydrocyanic acid are mandatory components of apricot kernel oil PEG-6 esters. (c) The concentration of amygdalin in a medicine must not exceed 10 mg/kg. (d) The concentration of hydrocyanic acid in a medicine must not exceed 10 mg/kg.

References – Requirements relating to amygdalin and hydrocyanic acid

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Appendix A – Ingredients in Permissible Ingredients Determination No. 2 of 2026 with requirements relating to hydrocyanic acid and/or amygdalin

Ingredient Name	Purpose	Requirements
ALMOND OIL	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Almond oil. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
BITTER ALMOND OIL	E	Bitter almond oil must only be included in medicines when in combination with other permitted ingredients as a flavour proprietary excipient formulation. The total concentration of flavour proprietary excipient formulations containing bitter almond oil must not be more than 5% of the medicine. The concentration of amygdalin in the medicine must not be more than 10 mg/kg.
ERIOBOTRYA JAPONICA	A, H	Amygdalin and hydrocyanic acid are mandatory components of Eriobotrya japonica. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
MALUS DOMESTICA	A, E, H	The concentration of amygdalin in the medicine must be no more than 0%.
PERSIC OIL	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Persic oil. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
PRUNUS AFRICANA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus africana. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.

PRUNUS ARMENIACA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus armeniaca and must be declared in the application. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
PRUNUS AVIUM	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus avium. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
PRUNUS CERASIFERA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasifera. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
PRUNUS CERASUS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus cerasus. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
PRUNUS DOMESTICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus domestica. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
PRUNUS DULCIS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus dulcis when the plant part is seed. When the plant part is seed, the maximum recommended daily dose must be no more than the equivalent of 1mg of the dry seed. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
PRUNUS HUMILIS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus humilis.

		The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
PRUNUS JAPONICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus japonica. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
PRUNUS LAUROCERASUS	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus laurocerasus. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
PRUNUS MUME	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus mume. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
PRUNUS PERSICA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus persica. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
PRUNUS SALICINA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus salicina. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
PRUNUS SEROTINA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus serotina. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.

PRUNUS SPINOSA	A, E, H	Amygdalin and hydrocyanic acid are mandatory components of Prunus spinosa. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
WILD CHERRY BARK DRY	A, H	Amygdalin and hydrocyanic acid are mandatory components of wild cherry bark dry. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.
WILD CHERRY BARK POWDER	A, H	Amygdalin and hydrocyanic acid are mandatory components of wild cherry bark powder. The concentration of amygdalin in the medicine must not be more than 10 mg/kg. The concentration of hydrocyanic acid in the medicine must not be more than 10 mg/kg.

Making a submission

The TGA is requesting comments that will help ensure that the proposed requirements are appropriate and support the quality and safety of listed and assessed listed medicines. To provide feedback on this consultation, please provide your submission using the file upload function on the Consultation Hub web page. You do not have to address all proposals. However, when responding, please clearly identify the proposal you are responding to.

Submissions may include any further data or information that may assist the Delegate to make an informed decision. Submissions may also include, for example, suggested improvements or an assessment of how the proposed change will affect you.

All submissions will be considered after the consultation period ends and may be published on the Consultation Hub web page with your consent.

Privacy and your personal information

The TGA collects your personal information in this submission in order to:

- Contact you if the TGA wants to seek clarification of issues raised in your submission or to check whether you consent to certain information that you have provided being made publicly available; and
- Help provide context about your submission (e.g. to determine whether you are an individual or a director of a company or representing an interest group).

The TGA may disclose your name, work title, company, and submission on the Internet (i.e. make this information publicly available) with your consent. You may specify whether there is anything in your submission which you would prefer to not be published online (e.g. names, email addresses, proprietary information) by:

- Providing an additional, redacted copy of your submission; or
- Providing details of content not to be published e.g. “Do not publish pages 3-5”, “Please redact contact details”; or
- Identifying any text within your submission to remain confidential by having it clearly marked ‘IN CONFIDENCE’ and highlighted in grey.

Please do not include personal information about other individuals in the body of your submission. Personal information in this context means information or an opinion about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion. The TGA will not publish personal information about you/others without your/their consent unless authorised or required by law.

Timetable

This consultation opened **02 November 2026**

Interested parties should respond by close of business **14 December 2026.** Please note that late submissions after this date may not be considered.

Following consideration of public submissions, outcomes of these proposals will be published to the Consultation Hub web page by **5 April 2027.**

The confirmed changes to the Determination will commence on **7 June 2027**.

The transition period of 1 year will end on **7 June 2028** unless otherwise specified.

Enquiries

Please contact us if you have any questions relating to this consultation at the following email address: nonprescriptionmedicines@health.gov.au.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	Complementary Medicines Evaluation Section, Complementary and OTC Medicines Branch	2 November 2026

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